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10/016,506	12/10/2001	James Pawlikowski	00-22	9080

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EXAMINER

KOPPIKAR, VIVEK D

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,506	Applicant(s) PAWLIKOWSKI ET AL.	
	Examiner Vivek D. Koppikar	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/10/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/4/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/10/03 & 12/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Claims 1-51 have been examined in this application. The Information Disclosure Statement (IDS) statements filed on February 10, 2003 and December 29, 2003 have also been acknowledged.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,305,374 to Zdorjkowski in view of US Patent Number 5,715,390 to Hoffman.

(A) As per claim 1, Zdorjkowski teaches a method of upgrading a medical device comprising (Zdorjkowski: Abstract):

providing a medical device having a controller that controls operation of the medical device according to an operating routine executed by the controller, wherein a set of operating features of the medical device is determined based on the operating routine (Zdorjkowski: Col. 3, Ln. 3-23 and Col. 14, Ln. 44-48).

Zdorjkowski does not teach or suggest the other claimed features, however, these are remaining features are all well known in the art as evidenced by Hoffman.

wherein an internal access key is associated with each set of operating features of the medical device (Hoffman: Col. 4, Ln. 52-57);

providing an external device adapted to communicate with the controller; establishing a

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communication link between the external device and the controller (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6);

inputting an external access key to the external device; comparing the internal access key provided by the medical device with the external access key (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6); and enabling upgrading of the medical device by enabling the operating routine to be modified responsive to the internal access key matching the external access key (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the method of Zdorjkowski with the aforementioned features from Hoffman with the motivation of providing a highly secure method of upgrading a device, as recited in Hoffman (Col. 36-38). (Note: Even though Hoffman is directed towards an electric meter the concept taught in Hoffman to upgrade an electric meter is the similar to the concept of the claimed invention. In addition, the concept of securely upgrading a device or controller in Hoffman can be applied to a variety of devices and machines).

(B) As per claim 2, in the combined method Zdorjkowski in view of Hoffman the medical device is a pressure support system comprising a pressure generating system adapted to generate a flow of breathing gas, wherein the controller executes a first operating routine to control the operation of the pressure generating system according to a first set of operating features (Zdorjkowski: Col. 3, Ln. 3-23).

(C) As per claim 3, the combined method of Zdorjkowski in view of Hoffman further comprises, after the enabling step, upgrading the medical device by providing a second operating routine from the external device to the controller, wherein the controller thereafter executes the

second operating routine causing the pressure support system to operate according to a second set of operating features (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

(D) As per claim 4, the combined method of Zdorjkowski in view of Hoffman the first set of operating features includes a first pressure support mode, and wherein the second set of operating features includes a second pressure support mode (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

(E) As per claim 5, in the combined method of Zdorjkowski in view of Hoffman the first pressure support mode is a bi-level pressure support mode, and wherein the second pressure support mode is a bi-level pressure support mode with a timed backup breath delivery capability (Hoffman: Col. 4, Ln. 51-59).

(F) As per claim 6, in the combined method of Zdorjkowski in view of Hoffman the step of establishing the communication link includes providing a hard wired connection between the external device and the controller (Hoffman: Col. 4, Ln. 23-27).

(G) As per claim 7, in the combined method of Zdorjkowski in view of Hoffman the step of inputting the external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device, or reading the external access key from a memory associated with the external device (Hoffman: Col. 4, Ln. 29-31).

(H) As per claim 8, in the combined method of Zdorjkowski in view of Hoffman further comprises the step of downloading the external access key to the controller responsive to the internal access key being input to the external device, and wherein comparing the internal access key with the external access key takes place in the controller (Hoffman: Col. 4, Ln. 57-63).

(I) As per claim 9, in the combined method of Zdorjkowski in view of Hoffman each internal access key associated with each set of operating features of the medical device is (1) generated by the controller based on an access key generating algorithm each time the comparing step is to be performed (Hoffman: Col. 4, Ln. 29-33), or (2) stored in advance in a memory in the medical device and recalled from the memory each time the comparing step is to be performed (Hoffman: Col. 4, Ln. 52-65).

(J) As per claim 10, in the combined method of Zdorjkowski in view of Hoffman, after the enabling step, upgrading the medical device by providing an upgraded operating routine from the external device to the controller, wherein the controller thereafter executes the upgraded operating routine causing the medical device to operate according to an upgraded set of operating features (Hoffman: Col. 1, Ln. 5-9).

(K) As per claim 11, in the combined method of Zdorjkowski in view of Hoffman, each internal access key associated with each set of operating features of the medical device is generated by the controller based on an access key generating algorithm each time the comparing step is to be performed, and further comprising storing the external access key in the medical device as a new internal access key, and causing the controller to generate the new internal access key in a subsequent access key validation process (Hoffman: Col. 4, Ln. 29-42).

(L) As per claims 12-21, the claims repeat features previously addressed in the rejection of claims 1-11, and are rejected on the same basis. (Note: These claims only differ from claims 1-11 in that they are directed towards a system rather than a method).

(M) As per claim 22, Zdorjkowski medical device upgrading system comprising (Zdorjkowski: Abstract): a medical device including:

processing means for controlling at least one operation of the medical device according to an operating routine executed by the processing means (Zdrojkowski: Col. 3, Ln. 3-23 and Col. 14, Ln. 44-48) , and

memory means, associated with the processing means, for storing the operating routine, wherein a set of operating features of the medical device is determined based on the operating routine, and wherein an internal access key is associated with each set of operating features of the medical device (Zdrojkowski: Col. 5, Ln. 48-57).

Zdrojkowski does not teach or suggest the other claimed features, however, these are remaining features are all well known in the art as evidenced by Hoffman.

Hoffman teaches an external device adapted to communicate with the processing means via a communication link between the external device and the processing means, wherein the external device includes means for receiving an external access key, wherein the processing means or the external device includes means for comparing the internal access key of the medical device with the external access key and for enabling upgrading of the medical device by enabling the operating routine to be modified responsive to the internal access key matching the external access key (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the device of Zdrojkowski with the aforementioned features from Hoffman with the motivation of providing a highly secure method of upgrading a device, as recited in Hoffman (Col. 36-38). (Note: Even though Hoffman is directed towards an electric meter the concept taught in Hoffman to upgrade an electric meter is the similar to the concept of the

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claimed invention. In addition, the concept of securely upgrading a device or controller in Hoffman can be applied to a variety of devices and machines).

(N) As per claim 23, the combined device of Zdorjkowski in view of Hoffman further includes a pressure generating system adapted to provide a flow of breathing gas to a patient under the control of the processing means, wherein the processing means executes a first operating routine stored in the memory to control the operation of the pressure generating system according to a first set of operating features (Zdorjkowski: Col. 3, Ln. 3-23).

(O) As per claim 24, in the combined device of Zdorjkowski in view of Hoffman the processing means is adapted to receive a second operating routine from the external device responsive to the external access key matching the internal access key, and wherein the processing means thereafter executes the second operating routine causing the pressure support system to operate according to a second set of operating features (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

(P) As per claim 25, in the combined device of Zdorjkowski in view of Hoffman the first set of operating features corresponds to a bi-level pressure support mode, and wherein the second set of operating features corresponds to a bi-level pressure support mode with a timed backup breath delivery capability (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

(Q) As per claim 26, in the combined device of the Zdorjkowski in view of Hoffman communication link is a hard wired connection between the external device and the processing means (Hoffman: Col. 4, Ln. 23-27).

(R) As per claim 27, in the combined device of the Zdrojkowski in view of Hoffman the external device includes a keypad by which the external access key is manually entered into the external device (Hoffman: Col. 4, Ln. 29-31).

(S) As per claim 28, in the combined device of Zdrojkowski in view of Hoffman the external device is adapted to download the external access key to the processing means, and wherein comparing the internal access key with the external access key takes place in the processing means (Hoffman: Col. 4, Ln. 52-65).

(T) As per claim 29, in the combined device of Zdrojkowski in view of Hoffman the processing means is adapted to generate each internal access key associated with each set of operating features of the medical based on an access key generating algorithm executed by the processing means each time an access key validation is required (Hoffman: Col. 4, Ln. 29-33).

(U) As per claim 30, in the combined device of Zdrojkowski in view of Hoffman the external device upgrades the medical device by providing an upgraded operating routine from the external device to the processing means responsive to an upgrade being enabled, wherein the processing means thereafter executes the upgraded operating routine causing the medical device to operate according to an upgraded set of operating features (Hoffman: Col. 1, Ln. 5-9).

(V) As per claim 31, in the combined device of Zdrojkowski in view of Hoffman the processing means generates each internal access key associated with each set of operating features of the medical device based on an access key generating algorithm each time an access key validation process is to be performed, stores the external access key in the medical device as a new internal access key, and generates the new internal access key in a subsequent access key validation process (Hoffman: Col. 4, Ln. 29-42).

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4. Claims 32-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdrojkowski in view of Hoffman and in further view of US Patent Number 6,094,702 to Williams et al.

(A) As per claim 32, Zdrojkowski teaches a method of upgrading a medical device (Zdrojkowski: Col. 25.Ln. 2-6).

However, Zdrojkowski does not teach the following features which are well-known in the art as evidenced by Williams:

providing an upgrade request from an upgrade requester to a medical device supplier, wherein the upgrade request includes a first product identifier associated with the medical device to be upgraded and a requested upgrade of the medical device (Williams: Col. 3, Ln. 43-57);

maintaining a database, available to the medical device supplier, that includes the first product identifier for the medical device and an external access key associated with both the medical device and an available upgrade (Williams: Col. 3, Ln. 57-64);

accessing the database, by the medical device supplier, to determine an external access key associated with both the medical device to be upgraded and the requested upgrade (Williams: Col. 3, Ln. 53-64).

updating the database to indicate that the medical device having the first product identifier has been upgraded with the desired upgrade (Williams: Col. 7, Ln. 14-23).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Zdrojkowski with the features of Williams with the

motivation of providing a means of installing resources into a system that are not enabled when a system is sold, as recited in Williams (Col. 2, Ln. 56-58).

The combined method of Zdrojkowski in view of Williams does not teach or suggest the following steps which are well known in the art as evidenced by Hoffman:

providing the external access key to the medical device (Hoffman: Col. 4, Ln. 52-57);
comparing the external access key with an internal access key associated with the medical device (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6);
enabling an upgrade of the medical device responsive to the internal access key matching the external access key (Hoffman: Col. 4, Ln. 52-Col. 5, Ln.).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the method of Zdrojkowski with the aforementioned features from Hoffman with the motivation of providing a highly secure method of upgrading a device, as recited in Hoffman (Col. 36-38). (Note: Even though Hoffman is directed towards an electric meter the concept taught in Hoffman to upgrade an electric meter is the similar to the concept of the claimed invention. In addition, the concept of securely upgrading a device or controller in Hoffman can be applied to a variety of devices and machines).

(B) As per claim 33, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the step of providing the external access key to the medical device includes providing the desired upgrade to the upgrade requester via a distribution media or a electronic communication link (Williams: Col. 3, Ln. 64-67).

(C) As per claim 34, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the step of providing the external access key and the desired upgrade includes

providing the external access key on a first medium and providing the desired upgrade on a second medium (Hoffman: Col. 4, Ln. 52-65).

(D) As per claim 35, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the step of comparing the external access key with an internal access key takes place in the medical device to be upgraded (Hoffman: Col. 4, Ln. 57-63).

(E) As per claim 36, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the step of updating the database includes providing a second product identifier (serial number) associated with the medical device (Hoffman: Col. 4, Ln. 47-51).

(F) As per claim 37, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the medical device includes a controller that controls operation of the medical device according to an operating routine executed by the controller (Zdrojkowski: Col. 3, Ln. 3-23), wherein a set of operating features of the medical device is determined based on the operating routine, wherein the internal access key is associated with each set of operating features of the medical device; and wherein providing the external access key to the medical device comprises: providing an external device adapted to communicate with the controller (Hoffman: Col. 4, Ln. 17-42), establishing a communication link between the external device and the medical device, and inputting an external access key to the external device (Hoffman: Col. 4, Ln. 17-42)

(G) As per claim 38, in the combined method of Zdrojkowski in view of Williams in view of Hoffman, after the enabling step, upgrading the medical device by providing an upgraded operating routine from the external device to the controller, wherein the controller thereafter

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executes the upgraded operating routine causing the medical device to operate according to an upgraded set of operating features (Hoffman: Col. 1, Ln. 5-9)

(H) As per claim 39, in the combined method of Zdrojkowski in view of Williams in view of Hoffman comprises the step of providing the upgraded set of operating features to the external device from the medical device supplier (Hoffman: Col. 1, Ln. 5-9).

(I) As per claim 40, in the combined method of Zdrojkowski in view of Williams in view of Hoffman each internal access key associated with each set of operating features of the medical device is generated by the controller based on an access key generating algorithm each time the comparing step is to be performed, and further comprising storing the external access key in the medical device as a new internal access key, and causing the controller to generate the new internal access key in a subsequent access key validation process (Hoffman: Col. 4, Ln. 17-42).

(J) As per claim 41, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the medical device is a pressure support system comprising a pressure generating system adapted to generate a flow of breathing gas, wherein the controller executes a first operating routine to control the operation of the pressure generating system according to a first set of operating features (Zdrojkowski: Col. 3, Ln. 3-23).

(K) As per claim 42, in the combined method of Zdrojkowski in view of Williams in view of Hoffman, after the enabling step, upgrading the medical device by providing a second operating routine from the external device to the controller, wherein the controller thereafter executes the second operating routine causing the pressure support system to operate according to a second set of operating features (Hoffman: Col. 1, Ln. 5-9).

(L) As per claim 43, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the first set of operating features includes a first pressure support mode, and wherein the second set of operating features includes a second pressure support mode (Zdrojkowski: Col. 3, Ln. 51-58).

(M) As per claim 44, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the first pressure support mode is a bi-level pressure support mode, and wherein the second pressure support mode is a bi-level pressure support mode with a timed backup breath delivery capability (Zdrojkowski: Col. 14, Ln. 43-48).

(N) As per claim 45, in the combined method of Zdrojkowski in view of Williams in view of Hoffman the step of establishing a communication link includes providing a hard wired connection between the external device and the controller (Hoffman: Col. 4, Ln. 17-24).

(O) As per claim 46, in the combined method of Zdrojkowski in view of Williams and Hoffman the step of inputting an external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device, or reading the external access key from a memory associated with the external device (Hoffman: Col. 4, Ln. 29-31).

(P) As per claim 47, in the combined method of Zdrojkowski in view of Williams and Hoffman the step of comparing the internal access key with the external access key takes place in the controller (Hoffman: Col. 57-65).

(Q) As per claim 48, in the combined method of Zdrojkowski in view of Williams and Hoffman each internal access key associated with each set of operating features of the medical device is (1) generated by the controller based on an access key generating algorithm each time

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the comparing step is to be performed (Hoffman: Col. 4, Ln. 29-33), or (2) stored in advance in the medical device and recalled from memory each time the comparing step is to be performed (Hoffman: Col. 4, Ln. 23-25).

(R) As per claims 49-51, the claims repeat features previously addressed in the rejection of claims 32-48, and are rejected on the same basis.

Conclusion

5. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").

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Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,



Vivek Koppikar

12/21/2005


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER